

The opinion in support of the decision being entered today was not written
for publication and is not binding precedent of the Board.

Paper No. 30

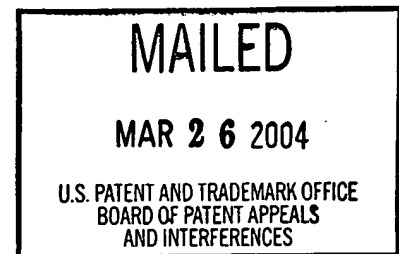
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte REID WARREN VON BORSTEL,
MICHAEL KEVIN BAMAT and
BRADLEY MARK HILTBRAND

Appeal No. 2002-1723
Application No. 08/463,740

ON BRIEF



Before WILLIAM F. SMITH, ADAMS and MILLS, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final
rejection of claims 41 and 58-67, which are all of the claims pending in this application.

Claim 41 is illustrative of the claims on appeal and reads as follows:

41. A composition comprising:

- a) an acyl derivative of uridine, cytidine or orotic acid, and;
- b) an inhibitor of uridine phosphorylase.

The prior art references relied upon by the examiner are:

Von Borstel	WO 89/03837	May 5, 1989
Chu et al (Chu)	4,613,604	Sept. 23, 1986

Grounds of Rejection

Claims 41 and 59-67 stand rejected under 35 U.S.C. 103(a) for obviousness over Von Borstel in view of Chu.

We affirm this rejection.

Claim Grouping

According to appellants the claims stand or fall together. Brief, page 4. Since the individual claims are not argued, we decide this appeal with respect to the prior art rejection on the basis of claim 41. 37 CFR §1.192(c)(7) (2000).

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief and Reply Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

35 U.S.C. § 103

Claims 41 and 59-67 stand rejected under 35 U.S.C. 103(a) for obviousness over Von Borstel in view of Chu.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

According to the examiner, Von Borstel disclose compositions comprising acylated uridine, cytidine, or orotic acid which are useful as prodrugs for increasing serum and intracellular free uridine. Answer, page 3. The examiner acknowledges that Von Borstel does not teach the combined use of acylated pyrimidine nucleosides and an inhibitor of uridine phosphorylase. Id.

To make up for this deficiency in Von Borstel, Chu is relied on by the examiner for its disclosure that uridine phosphorylase inhibitors potentiate the chemotherapeutic effect of pyrimidine nucleoside analogs such as 5-fluorouridine (column 2, lines 36-59) by elevating the levels of free uridine. Id.

The examiner summarizes (Answer, pages 3-4) that

it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the prodrugs of uridine disclosed by Von Borstel et al. with the uridine phosphorylase inhibitors taught by Chu et al. for the purpose of elevating even higher the free uridine levels in the serum and inside the cells.

Appellants respond to the examiner's position, arguing that Chu relates to the use of compounds uridine phosphorylase inhibitors in the treatment of cancer and "has nothing to do with compositions suitable for use in the treatment of inflammatory disorders." Brief, page 7.

We are not persuaded by this argument. Claim 41 before us is not directed to a method of use, claim 41 is a composition claim. Thus, arguments relating to the intended use of a composition are not relevant to the composition claim 41 before us.

Appellants argue that the focus of Chu is to prevent the cleavage of the nucleoside analog to a less effective material, and not to elevate uridine levels. Brief, page 8. Appellants also argue that the compounds of Chu are indicated to reduce phosphorolytic degradation of FdUrd (5-fluoro-2'-deoxyuridine) to the less active FUra (5-fluoro uracil) in tumor cells. Id.

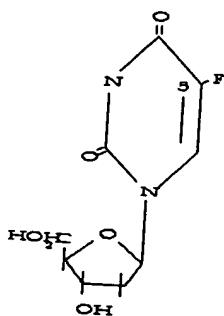
Appellants submit that Chu is not relevant to the disclosure of Von Borstel and does not remedy the absence of a prima facie case of obviousness. Brief, page 9.

Appellants conclude (Brief, page 8) arguing that

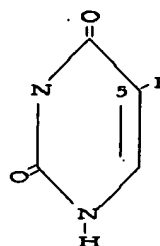
[i]t is not seen how such motivation could possibly arise in the mind of a person of ordinary skill in the art in view of the disclosures of the cited references. Absent any such motivation to combine these disclosures, it is clear that a *prima facie* case of obviousness has not been established in this case.

The examiner responds to appellants, suggesting that "a specific object of Chu et al. is to provide novel uridine phosphorylase inhibitors which reduce phosphorolytic degradation of a uridine derivative. As also acknowledged by applicant, (on p. 19 of the specification, 3rd paragraph) uridine is incorporated into cellular nucleotide pools by phosphorylation at the 5' position; thus compounds which reduce phosphorolytic degradation of uridine derivatives would clearly increase or maintain the amount of uridine available for incorporation into the cellular nucleotide pool." Answer, page 5. The examiner argues that Chu provides the motivation to use uridine phosphorylase inhibitors with other compounds useful for increasing free uridine, and the fact that the anti-degradative effect in Chu is demonstrated with tumor cells "does not diminish the correlation between maintaining phosphorylation of a uridine derivative and the availability of free uridine within the cellular nucleotide pool." Answer, page 5.

We agree that the examiner has provided evidence of an appropriate reason, suggestion or motivation to combine the cited references. In particular, Chu describes that FdUrd, a chemotherapeutic, degrades to less active 5-fluorouracil by cleavage of the sugar or ribose portion FdUrd through the action of uridine phosphorylase.



5-fluoro-2'-deoxyuridine



5-fluoro uracil

Chu found that inhibitors of uridine phosphorylase reduce the phosphorolytic degradation of FdUrd to the less active compound 5-fluorouracil. Chu, column 1, line 67 to column 2, line 2. In so doing, Chu increased the levels of FdUrd present. The examiner indicates that one of ordinary skill in the art desiring to avoid degradation of acyl derivatives of uridine to uracil and thus increase levels of acyl derivatives of uridine, would also look to prevent or inhibit the degradative effect of uridine phosphorylase.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.'" Ecolochem, Inc. v. Southern Calif. Edison Co., 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075 (Fed. Cir. 2000) (quoting In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998)).

In the present case, the examiner has indicated and provided sufficient evidence of the specific technical or scientific reasoning, understanding or principle within the knowledge of a skilled artisan, explicit or implicit, that would have motivated one with no knowledge of appellants' invention to make the combination in the manner

claimed. In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998).
In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000).

On the facts and record before us, we find that the examiner has established a prima facie case of obviousness which has not been rebutted by appellants. The rejection of claims 41 and 59-67 under 35 U.S.C. 103(a) for obviousness over Von Borstel in view of Chu is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED


WILLIAM F. SMITH
Administrative Patent Judge


DONALD E. ADAMS
Administrative Patent Judge


DEMETRA J. MILLS
Administrative Patent Judge

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